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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,185	05/03/2001	Jay M. Short	DIVER1280-11	6495

7590

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EXAMINER

LOEB, BRONWEN

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 11/05/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/848,185

Applicant(s)

SHORT ET AL.

Examiner

Bronwen M. Loeb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 7 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-19 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-19 and 21-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 07 August 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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The following papers have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 CFR 1.52(a)) because of damage from the United States Postal Service irradiation process:

Mailroom Stamp Date

Certificate of Mailing Date

7 AUG 2002

2 AUG 2002

Papers 10-12

The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

**COPY OF PAPERS  
ORIGINALLY FILED**

If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 CFR 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 CFR 1.19(b)(4). Please do **not** call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will **not** be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within **THREE MONTHS** of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-identified papers (*i.e.*, the Office will use the copy of the above-identified papers made by the Office for examination and all other purposes). This three-month period is not extendable.

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### DETAILED ACTION

This action is in response to the amendment filed 7 August 2002 in which claims 1-3, 5, 6, 9, 21 and 23 were amended, claims 7 and 20 were cancelled and new claims 27 and 28 were presented.

Claims 1-6, 8-19 and 21-28 are pending.

### *Drawings*

1. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 7 August 2002 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.
2. The Patent and Trademark Office no longer makes drawing changes. See 1017 O.G. 4. It is applicant's responsibility to ensure that the drawings are corrected. Corrections must be made in accordance with the instructions below.

### INFORMATION ON HOW TO EFFECT DRAWING CHANGES

#### 1. **Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be

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obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

**2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

***Claim Objections***

3. Claim 26 is objected to because of the following informalities: Claim 26 claims dependency on claim 25. While this is acceptable with respect to antecedent basis, the recitation in claim 26 appears unrelated to the recitation to that in claim 25. The Examiner wonders if Applicant meant to claim dependency to claim 24. Appropriate correction is required.

***Response to Amendment***

4. The rejection of claims 1-6 and 8-26 under 35 USC §112, second paragraph, as being indefinite, has been withdrawn in view of Applicant's amendment.

The rejection of claim 20 under 35 USC §102(e) as being anticipated by Thompson et al (USP 5,824,485) has been withdrawn in view of Applicant's amendment.

The rejection of claim 20 under 35 U.S.C. §103(a) as being unpatentable over Thompson et al as applied to claims 1-5, 8-18 and 24-26 above, and in view of Short (USP 5,958,672) has been withdrawn in view of Applicant's amendment.

5. Claims 1-5, 8-18 and 24-26 stand rejected under 35 USC §102(e) as being anticipated by Thompson et al.

Claims 1-6, 8-19 and 24-26 stand under 35 U.S.C. §103(a) as being unpatentable over Thompson et al as applied to claims 1-5, 8-18 and 24-26 above, and in view of Short.

6. New grounds of rejection, necessitated by Applicant's amendment, are presented below.

### ***Response to Arguments***

7. With regard to the rejection of claims 1-5, 8-18 and 24-26 rejected under 35 USC §102(e) as being anticipated by Thompson et al, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that Thompson et al is deficient because specific aspects of the claimed invention are not disclosed. Specifically, Applicant states that Thompson et al fails to teach co-encapsulation in a liposome, gel microdrop, beads, agarose, cell, ghost red blood cell or ghost macrophage, and also fails to disclose DNA probes that

comprise a detectable label. These arguments are not persuasive. Thompson et al clearly teach co-encapsulation in agarose or microdroplets for the purposes of screening or pre-screening. See col. 33, 53-57 and col. 37, line 38-col. 38, line 53. Thompson et al further teach the use of hybridization of molecular beacon DNA probes for pre-screening or screening of a library. See col. 37, lines 32-33. Molecular beacon DNA probes are nucleic acid probes that fluoresce upon hybridization (see Tyagi et al (1996) Nature Biotechnology 14:303-308).

Thompson et al clearly teach for pre-screening for an activity of interest (col. 33, lines 28-30), including enzymes (col. 32, lines 28-56) using hybridization to a probe; since probe hybridization relies on the sequence, the probe taught by Thompson et al would have to comprise sequence encoding at least part of the sequence of interest.

Therefore, Applicant's arguments are not persuasive and the rejection is maintained.

8. With regard to the rejection of claims 1-6, 8-19 and 24-26 under 35 U.S.C. §103(a) as being unpatentable over Thompson et al as applied to claims 1-5, 8-18 and 24-26 above, and in view of Short, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that Thompson et al is deficient and that Short does not make up for the alleged deficiencies in Thompson et al. As discussed above, Thompson et al is not a deficient reference. Therefore, this argument is not persuasive and the rejection is maintained.

**New Grounds of Rejection**

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-6, 8-19 and 21-28 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, 27 and 28 are vague and indefinite in reciting "a detectable label". The specification teaches that a detectable label may include ligand and specific binding partners (see p. 30 [0094]) and teaches how to use such labels for *selection*. However, it is unclear how the subsequent *screening* step can be carried out if the one binding partner is within the encapsulated microenvironment containing the mixture of target DNA and DNA probes and is thus not accessible for binding to its binding partner.

Claim 24 recites the limitation "the detectable marker" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Conclusion***

Claims 1-6, 8-19 and 21-28 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP



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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

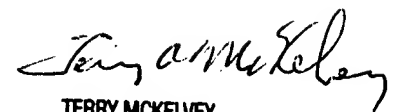
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

Customer service for Tech Center 1600 may be reached at (703)-308-0198.

Bronwen M. Loeb, Ph.D.  
Patent Examiner  
Art Unit 1636

October 24, 2002

  
TERRY MCKELVEY  
PRIMARY EXAMINER